ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Validation Manager

Speaker

Robert Schwarz
FH Campus Vienna, Austria

Cleaning Validation

Live Online Training on 3/4 September 2020

Three Q & A sessions make it lively

Highlights

- Regulatory Requirements
- Hygienic Equipment Design
- Cleaning Process Development
- Cleaning Validation, incl. Practical Approaches
- Sampling
- Handling Deviations and OOS
- Segregation and Shared Facilities
- Cleaning Validation in Biologics and Biotech Production

Background

In the manufacture of medicinal products and APIs, the cleaning of facilities and equipment is an important measure to avoid contamination and cross contamination. In compliance with the GMP regulations, cleaning is performed and documented according to the described procedures. In the past, cleaning effectiveness was often monitored only visually. However, residuals of APIs and excipients as well as of detergents are increasingly an issue in inspections and audits. The success of cleaning procedures has to be validated. In addition to the FDA "Guide to Inspection – Validation of Cleaning Validation Processes", the PIC/S document PI 006 and Annex 15 address cleaning validation in a separate chapter. Moreover, the ICH Guideline Q7 "GMP for APIs" also requires cleaning validation – as well as two guidelines by APIC, the association of European API manufacturers.

A Guideline from EMA on Dedicated Facilities and Exposure Limits for Cleaning Validation and the revised Annex 15 deal now with a PDE (Permitted Daily Exposure) approach

Objective

Many questions relative to cleaning validation are still open and have to be answered within the companies:

- What does the cleaning validation concept have to look like to be GMP-compliant and cost-effective?
- Which risk analyses are applicable to cleaning validation?
- How helpful can a riboflavin test be?
- Which maximum value is scientifically acceptable, especially in the field of APIs?
- Which sampling procedure is appropriate for which process and facility?
- How can you cut costs by means of bracketing?
- How are critical areas defined?
- Is cleaning evaluation the solution for seldom manufactured products?
- Which microbiological maximum values are valid in the areas of non-sterile dosage forms and APIs?
  and
- What are special aspects of cleaning validation in biotech API plants?

These questions will also be discussed with the help of practical examples.

Target Audience

This course is directed at staff of R&D, production and quality assurance involved in cleaning validation. It also addresses engineering companies and manufacturer of cleaning devices/equipment interested in learning more about the pharmaceutical industry's viewpoint and in exchanging experiences.

To ensure a high quality transmission the presentations of this seminar was recorded in advance.

Q & A sessions
Three Q &A sessions (two on day 1 and one on day 2) ensure interaction and that your questions are answered

Programme

Day 1

09.00 - 10.15 h
Regulatory Requirements

- EU GMP Guideline Part I, II and III
- EU GMP Guideline Annex 15
- EMA "Shared Facilities Guideline" (incl. PDE concept)
- PIC/S PI 006
- APIC Cleaning Validation Guidance for APIs
- PDA TR 29 – "Points to Consider for Cleaning Validation
- FDA 21 CFR 211.67
- FDA Guide to Inspection – Validation of Cleaning Processes

10.15 - 11.00 h
Practical pre-requisites I – Hygienic Equipment Design

- What is hygienic design?
- Material aspects
- WIP/CIP aspects
- Riboflavin test

11.00 - 11.30 h Break

11.30 - 13.00 h
Practical pre-requisites II – Cleaning process Development

- Developing a cleaning process – which steps are necessary?
- TACT
- Which residues are common
- Type and selection of cleaners
- CIP vs WIP vs manual cleaning
- Cleaning Documentation

13.00 - 14.00 h Break

14.00 - 14.30 h Q & A

14.30 - 16.00 h
Cleaning Validation – incl. practical Approaches

- Cleaning Validation Concepts
  - Bracketing
  - Hold time studies (DHT, CHT)
- Cleaning Validation Risk Management
- Cleaning Validation Plan
- Cleaning Validation Report
- Cleaning Validation life cycle (Revalidation, Ongoing Cleaning Verification)
- Cleaning Evaluation

16.00 - 16.30 h Q & A

Day 2

09.00 - 10.10 h
Sampling during Cleaning Validation

- How to define sampling points?
- Sampling techniques
  - Swab
  - Rinse
  - Coupons
- Analytical requirements

10.10 - 10.30 h Break

10.30 - 11.45 h
Handling Deviations and OOS during Cleaning Validation and Ongoing Cleaning Verification

- What is an OOS, what a deviation regarding Cleaning Validation?
- GMP-compliant documentation of OOS and deviations
- CAPA

11.45 - 12.00 h Break

12.00 - 13.20 h
Special Topics of Cleaning Validation

- Segregation & shared facility guideline
- Cleaning Validation in Biologics & Biotech production
  - Differences between chemical and biotech APIs
  - Acceptance criteria for biotech APIs
  - Analytical methods to detect biotech APIs in Cleaning Validation

13.20 - 13.45 h Q & A

Speaker

Robert Schwarz
FH Campus Vienna, Austria

Robert has 20 years hands-on experience in aseptic processing, contamination control and cleanroom technology. He graduated in bioengineering and biotechnological quality management and joined Baxter, Vienna in 2001 where he led the environmental monitoring team 4 years. 2005 - 2018 he gathered more in-depth knowledge of GxP compliance incl. profound quality assurance expertise in his function as validation specialist being responsible for equipment qualification, sterilization validation and cleaning validation (with an SME function since 2016) at Baxter and Shire. Since 2010 he additionally shares his experience as a university lecturer. Additionally he's frequently spotted as a speaker at congresses and conferences and recognized as a contributor in various scientific publications. In 2019 he started his business as freelancing trainer and consultant.

GMP and GDP In-house Training Programme

What are GMP/GDP In-house Training Courses?
GMP/GDP in-house Training Courses are an ideal solution and a cost-effective way to train a larger number of people (ten or more) than you would normally want to send to an external course. You determine date and time, and the training is provided in your premises – or, alternatively, online, as most of the trainings can also be conducted via Internet.

Why GMP/GDP In-house Training?
Our GMP/GDP in-house trainings help your employees to put the GMP/GDP requirements into practice, to understand why they have to observe GMP/GDP rules and to develop a positive attitude towards GMP/GDP. In discussing of questions, your staff becomes familiar with the GMP/GDP rules, and solutions to concrete problems are found.

The courses you can choose from
Training content depends on your individual needs and ideas. A course can take into account the specific situation in your company and considers the latest GMP publications. Then both the training course's content and structure are tailored to the target group - also considering group-dynamic effects.

Now online
Almost all of our in-house trainings can also be conducted online. This allows for maximum flexibility since your employees can take part in the same session no matter where they are located.

Professional GMP Trainers
Your GMP trainers have been working for us as speakers for many years. Only GMP trainers with a track record from our open GMP Education Courses or European Conferences can conduct in-house training courses as associated partners. Each special field is covered by a different trainer. This way you can be sure that you have a competent GMP trainer, no matter if the course is about current Part 11 trends or about cleanrooms for aseptic manufacture.

Documentation and Certification
Every participant receives a folder with detailed training documentation. As a recognised organisation for advanced training, we issue certificates that document the participation in the training measure and that are accepted by the supervisory authorities.

Please visit our website www.gmp-compliance.org for more information.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Cleaning Validation - Live Online Training on 3/4 September 2020

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERGwill not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Thursday , 3 September 2020,
09.00 – 16.30 h
Friday, 4 Septembery 2020,
09.00 – 13.45 h

Technical Requirements

For our webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in.
Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,290
APIC Members € 1,390
Non-ECA Members € 1,490
EU GMP Inspectorates € 745
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)6221/84 44 0
Fax +49(0)6221/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Mr Sven Pommeranz (Operations Director) at
Phone +49(0)6221/84 44 47, or at
pommeranz@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Julia Grimmer (Organisation Manager) at
Phone +49(0)6221/84 44 44, or at
grimmer@concept-heidelberg.de.